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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,371	02/15/2002	Kalyan Handique	10255-029-999	9738
26171	7590	12/29/2004		EXAMINER
FISH & RICHARDSON P.C. 1425 K STREET, N.W. 11TH FLOOR WASHINGTON, DC 20005-3500			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 12/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,371	HANDIQUE ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1-3,5-8 and 10-28 is/are rejected.
- 7) Claim(s) 4 and 9 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 February 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____.

DETAILED ACTION***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

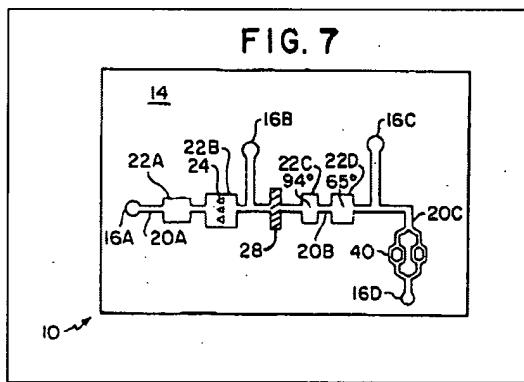
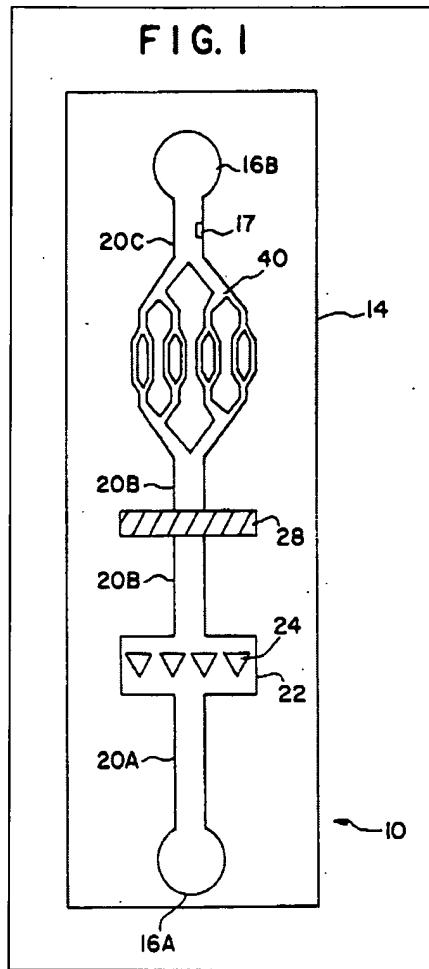
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 3, 5 – 8, 11 – 18, 20, 22, 23 and 25 – 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (U.S. Pat. No. 5,635,358 A) in view of Brody (U.S. Pat. No. 5,726,404 A). Regarding claims 1, 12, 13, 26 and 28, Wilding et al. teach a microfluidic apparatus comprising various spaced apart locations (e.g., 20A, 20B, 22C, 22D, etc.) contained within the apparatus for processing a sample. Wilding et al. do teach the incorporation of a fluid flow control system incorporating the use of pumps (see col. 10, lines 44 – 62; col. 8, lines 52 – 66; figures 1 & 7). Furthermore, with regards to claim 26, Wilding et al. teach a microfluidic network comprising a plurality of chambers and interconnecting channels (see figure 4 & 7). Wilding et al. do not specifically teach the incorporation of a gas actuator system for providing fluid flow control. However, gas actuated fluid flow control systems for microfluidic devices are

well known in the art, as is evidenced by Brody (see col. 4, lines 32 – 67; col. 6, lines 57 – 60). Hence, it is deemed reasonable that a person of ordinary skill in the art would have recognized that these two disclosed fluid flow control mechanisms are considered functionally equivalent in the art of microfluidic devices (see MPEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Additionally, as shown by Brody, a person of ordinary skill in the art would have recognized the suitability of using a gas actuated mechanism within a microfluidic apparatus for the same intended purpose of facilitating sample fluid flow control within the microfluidic apparatus (see MPEP § 2144.07). Furthermore, as evidenced by Brody, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating a gas actuated fluid flow control mechanism within an analytical microfluidic device. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a gas actuated pumping mechanism to facilitate sample fluid movement, as taught by Brody, with the Wilding et al. microfluidic apparatus, in order to facilitate effective sample fluid transfer and processing within the apparatus.



Regarding claim 5, Wilding et al teach that a first location which is a processing location, such as a separation chamber 22A (see figure 7). Regarding claims 6 and 15, Wilding et al. teach the incorporation of enrichment zones (e.g., sections 22C & 22D) (see figures 1 & 7).

Regarding claims 7 and 16, Wilding et al. teach the incorporation of a cell lysing zone (e.g., cell handling zone 22 comprising cell piercing or rupturing protrusions 24) (see figure 1). Regarding claims 8 and 17, Wilding et al. teach the incorporation of a downstream detection region (e.g., fractal detection region 40) (see col. 9, lines 1 – 5). Regarding claims 11, 14, 25 and 27, Wilding et al. teach the incorporation of valves to control fluid flow within the apparatus (see col. 10, lines 10 – 67). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an integrated valve system with the gas actuation system to facilitate effective sample fluid control within the apparatus. Regarding claim 18, Wilding et al. do teach that the disclosed apparatus may be utilized for PCR (see col. 10, lines 10 – 27).

Regarding claims 4, 6, 7, 15, 16 and 18, these claims recite various process or intended use limitations, such as what kind of sample is processed, for example, which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. Recited process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that

old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Regarding method claims 20, 22, 23 and 25, as discussed above, Wilding et al. in view of Brody teaches all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). Furthermore, regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Wilding et al. and Brody, as such is the intended operation of that apparatus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 19, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. (U.S. Pat. No. 5,635,358 A) in view of Brody (U.S. Pat. No. 5,726,404 A).

Neither Wilding et al. nor Brody specifically teach an integrated gas actuator construction.

However, the Courts have held that the use of a one-piece, integrated construction instead of the structure disclosed or taught in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965).

Therefore, it would have been obvious to a person of ordinary skill in the art to provide an integrated construction for the apparatus taught by Wilding et al. in view of Brody to provide for the claim limitations of claims 10, 19 and 21.

Regarding method claims 21 and 24, as discussed above, Wilding et al. in view of Brody teaches all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02). Furthermore, regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed

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properties or functions are presumed to be inherent (see MPEP § 2112.01). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Wilding et al. and Brody, as such is the intended operation of that apparatus.

Allowable Subject Matter

Claims 4 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 4, the cited prior art neither teach nor fairly suggest the further incorporation within the apparatus taught by Wilding et al. in view of Brody a second location which overlaps the third location.

Regarding claim 9, the cited prior art neither teach nor fairly suggest the further incorporation within the apparatus taught by Wilding et al. in view of Brody a gas actuator each comprising a heat source for facilitating thermal actuation.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Burns et al. teach the utilization of thermal microvalves in microchannels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Jill A. Warden".